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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,965	10/31/2003	Gerrit Reinold Melles	05032-00045	8819
22910	7590	06/21/2006	EXAMINER	
BANNER & WITCOFF, LTD. 28 STATE STREET 28th FLOOR BOSTON, MA 02109-9601			MILLER, CHERYL L	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 06/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/698,965	MELLES, GERRIT REINOLD	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 15-17 and 25-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 18-24, 29-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed April 7, 2006 have been fully considered but they are not persuasive.

The applicant has argued that the publication www.stlukeseye.com/Conditions/ForeignnBody.asp does not disclose an implant capable of being placed in the eye. The examiner disagrees. Stlukes shows clearly in the figures, a nail chip embedded in the eye, therefore, clearly, the object is *capable* of being placed in the eye. Whether or not it is harmful or irritating is irrelevant. This is a product claim. Stlukes contains all structural features claimed and has even shown the object within the eye. The applicant has also argued that Stlukes has not disclosed a surgical method to implant the object. This argument is moot also, since the Stlukes reference has not been used to reject a method of implantation claim, only product claims have been rejected by Stlukes. The applicant has also argued that Stlukes's object is not flat. Stlukes discloses a chip of a nail, chips, by definition has a flat surface, thinner than its width. This rejection has been maintained.

The applicant has argued that Young (US 6,656,222) does not disclose an implant capable of fitting in or on the iris, conjunctive, sclera, or cornea. The examiner disagrees. Young discloses all structural features of the claim. Young's implant is placed inside the eye, as required by the independent claim. Young's implant is also capable of being placed *on the iris or cornea* and additionally has attachment means (haptics) for attaching the implant to the conjunctiva, sclera, cornea, or iris (that is, clearly the implant of Young is capable of fitting in the anterior chamber of the eye, wherein the attachment structures, haptics would contact these

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structures of the eye; and further in this case, the opaque region of the implant would be seen from outside of the eye). The applicant has argued that Young does not disclose a container. It is first noted to the applicant, that a container is not part of an "eye implant". That is, an eye implant can not comprise a container, since the container is not implanted. Further, all implantable devices are contained during sterilization inherently if they are to be placed in the body. This rejection has been maintained.

The applicant has also argued that Lynch (US 6,783,544) does not disclose an implant for placement between the conjunctiva and the sclera. The examiner disagrees. First the implant disclosed by Lynch is *capable* of being placed anywhere within the eye. Second, Lynch shows the implant clearly between the conjunctiva and the sclera in the figures. This rejection has been maintained.

In summary to the majority of the applicant's arguments, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 7-9, 12-14, and 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by site publication www.stlukeseye.com/Conditions/ForeignBody.asp (cited previously), previously published on 11/23/01 and 08/08/02, see http://web.archive.org/web/*/http://www.stlukeseye.com/Conditions/ForeignBody.asp . The site discloses a flat element, either a grain of sand or a chip of a nail embedded in the eye, both of which may be considered an “eye implant”. *Metal and sand are disclosed by the applicant to be examples of biocompatible elements that are opaque for use with this invention, and such elements are disclosed in the above site.* The sand or nail chip disclosed on the site is *capable of* being used as a cosmetic implant and is *capable of* being sterilized (it is noted to the applicant that this is intended use language, and the element disclosed on the site is *capable of* being used in this manner). The element disclosed on the site has an attachment means (any sharp edge on the sand or nail chip may be considered a means of attachment). The element disclosed in the site is capable of being implant on or in the conjunctiva (see paragraph under heading treatment). The element is disclosed to be multiple particles (multiple particles of sand).

Claims 1-3, 6-14, 18-21, and 30-31 are rejected under 35 U.S.C. 102(e) as being anticipated by Young et al. (US 6,656,222 B2, cited previously). Young discloses an eye implant comprising a flat biocompatible element (13) being made of at least partly opaque or light reflecting (portion 21; col.2, lines 4-8, 50-55), such to be visible outside the eye. Young discloses the element (13) to be disc shaped (fig.1, 7) with rounded edges (fig.4, 10). Young discloses an implant made of PMMA (col.4, lines 17-23). Young discloses an implant *capable of* being used as a cosmetic implant and *capable of* being sterilized (it is noted to the applicant

that this is intended use language and the implant disclosed is capable of being used in this manner). Young discloses a concave and convex surface (convex and other known shapes, col.4, lines 15-17). Young discloses an attachment means (haptics 15, 17). Young's implant is *capable of* being positioned in or on the conjunctiva of the eye. Young's implant may comprise multiple particles (15, 17, 13, 21; or each protrusion of 21 may be considered a particle). Young's implant inherently comes in a container, since it is an implant for implantation in the body and therefore needs to be provided in a sealed sterilized container as all surgical material is.

Claims 1, 2, 6-10, 12-14, 18-23, and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Lynch et al. (US 6,783,544 B2, cited previously). Lynch discloses an eye implant comprising a flat biocompatible element (10; fig.3) at least partly opaque or light reflecting (inherently opaque, since the same materials are used as the applicant has claimed, metals, PMMA; col.6, lines 15-25), that is visible outside the eye. Lynch discloses a method for implanting an element in the eye comprising providing a partially at least opaque element, providing an opening in the conjunctiva, dissecting part of the conjunctiva, and closing the opening (col.6 line 57-col.7 line 7).

Claim 29 is rejected under 35 U.S.C. 102(e) as being anticipated by Snyder (US 6,899,733 B2). Snyder discloses a set comprising an eye implant (haptics 14) comprising a flat element made of biocompatible material that is partly opaque or light reflecting (metals, such as nitinol, stainless steel and titanium, being opaque or light reflecting in nature; col.4, lines 1-3; see figs), such that they would be visible in the eye (inherently they would, since they are opaque

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and light reflecting; further, Snyder also discloses the capability of implanting the haptic in the iris; col.4, lines 7-14) a scalpel, visco elastic material (col.4, lines 24-30), and forceps (col.6, lines 3-10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al. (US 6,656,222 B2, cited previously). Young discloses an eye implant for placement in the eye, however is silent to any specific dimension for the implant. It would have been an obvious matter of design choice to have the dimension claimed, since such a modification would have only involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch et al. (US 6,783,544 B2, cited previously). Lynch discloses a method of implantation of an eye implant in or on the conjunctiva, near the limbus (see fig.4). Lynch is silent however as to what exact distance (how close) the implant is located from the limbus. It would have been obvious to place the implant as close as 2-5 mm to the limbus, since wherein the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cheryl Miller

**BRUCE SNOW**
PRIMARY EXAMINER